

IN THE DISTRICT COURT OF CLEVELAND COUNTY STATE OF OKLAHOMA

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STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, vs.))))) Case No. CJ-2017-816) Judge Thad Balkman
 (1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA, INC.; (5) CEPHALON, INC.; (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, INC; (8) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS; (9) JANSSEN PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; (11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; and (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., 	Special Master: William Hetherington STATE OF OKLAHOMA CLEVELAND COUNTY S.S. FILED AUG 2 4 2018 In the office of the Court Clerk MARILYN WILLIAMS
Defendants.)

THE STATE'S RESPONSE TO <u>PURDUE'S MOTION TO COMPEL PRODUCTION OF DOCUMENTS</u>

The State respectfully requests the Court deny the Motion to Compel Production of Documents filed by Purdue Pharma, L.P. and The Purdue Frederick Co. (collectively, "Purdue") in its entirety. The Motion is premature and unnecessary, and it represents yet another transparent attempt by Purdue to thwart an orderly discovery process and avoid a May 2019 trial date. In support of this Response, the State states as follows:

INTRODUCTION

Purdue's *Motion* is nothing short of frivolous and a waste of this Court's time and resources. The fundamental errors in Purdue's *Motion* are three-fold. First, the Court already ruled on the issues raised in the *Motion*, and the State continues to comply with the Court's discovery rulings to provide a "rolling production" of documents. Purdue's continuous comparison of the number of documents produced by the parties is meaningless. Second, many of the issues set forth in Purdue's *Motion* have been or will be mooted by the State's document productions. Third, Purdue ignored its obligation to conduct a meet and confer prior to any discovery motion being filed, and instead, misrepresents to the Court that it tried to meet and confer with the State "but received no response." That is par for the course for Purdue's misleading representations of what happened.

As explained in more detail below, Purdue's Motion should be denied.

ARGUMENT AND AUTHORITIES

A. <u>The State Continues To Comply With The Court's Order To Produce Documents On</u> <u>A Rolling Basis</u>.

The State has complied and will continue to comply with Judge Hetherington's rulings on document production. Purdue misrepresents the nature of responsive material the State has produced. Judge Hetherington already addressed the State's responses to Purdue Frederick Co.'s *Request for Production Nos. 1, 5,* and 6, finding the "State's objection withdrawn during meet and confer" and sustaining Purdue Frederick Co.'s motion on those requests. [*Ex. 1, Orders of Special Discovery Master on April 19, 2018 Motion Requests (04/25/18) at p. 3.*] Judge Hetherington further stated: "Therefore, both Purdue Pharma L.P. and Purdue Frederick Company's motion to compel are **sustained** to be produced <u>as soon as practically possible under the agreed 'rolling production' process</u>." [*Id. at p. 2* (bold in original; underline added)]. The State has been producing

documents on a rolling basis as quickly as it can. <u>The State began producing documents on April</u> <u>10</u> and, since the April 25 ruling, the State has made sixteen different production volumes consisting of over 30,000 pages of documents from more than six different state agencies.¹ Further, Purdue's repeated representation the State has only produced "three documents" from the OHCA is simply wrong. Indeed, the State has already produced many of the documents regarding *Purdue Frederick Request for Production Nos. 1, 5* and *6* about which Purdue complains. Indeed, Purdue has had these documents since April 10, which include publicly available information from the OHCA website that is responsive to this particular request. The production includes more than 450 documents and over 17,000 pages. That is a far cry from the "three documents" Purdue claims in its Motion.

Purdue's misrepresentation regarding the State's discovery responses is further misleading, as it wholly ignores the detailed Interrogatory answers the State has provided on these issues. [See, e.g., Ex. 2, State's Responses to Purdue Pharma, L.P.'s First Set of Interrogatories (02/14/18) at ROG Nos. 1, 4-5.] These detailed Interrogatory answers, some of which provide more than seven pages of information, also provide citations to relevant, responsive, and publicly available documents. In other words, Purdue cannot credibly complain that they only have "three documents" and have no other information related to these requests.

Further, the State's counsel assured the Court that Defendants' counsel would have all documents they need to proceed with their depositions in a timely manner. [*Ex. 3, Hearing Transcript (08/10/18) at pp. 46-47* ("Number one, on timing, if they want to take depositions of our clients, they've got a lot of time to do it. As Mr. Whitten once told Judge Hetherington, we'll

¹These figures do not include documents received from third parties or non-parties which the State has also produced to Defendants.

make ourselves available. They've got plenty of time. They don't have the documents they need? They'll get them. They can take those depositions.")]. The State has every intention of making good on that promise. The State has complied with the terms of production set forth by the Special Discovery Master to produce documents on a rolling basis, and it will continue to do so.

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Moreover, Purdue's continued insistence that the <u>size</u> of Plaintiff's document production entitles it to an order compelling documents is a red herring. First, it is no surprise that Purdue is in possession of the majority of responsive documents in this case. They spent the last two decades creating a nationwide opioid epidemic. They have spent billions of dollars and many years sending their salespeople into the medical community armed with misinformation intended to exaggerate the benefits of opioids and downplay their addictive qualities. Given the widespread nature of Purdue's wrongful conduct and the amount of time it has gone on, it is not surprising the volume of their document production is staggering.

Second, comparing the number of documents produced by the parties is meaningless. The quality and nature of the documents is all that matters. The State is engaging in a document production specifically targeted at the categories of documents Purdue has requested, and it is doing so as quickly as possible (and with extremely limited resources and a budget which has only been worsened by the cost of the opioid epidemic). The quality of the State's document production should be the Court's focus—not its size. *See, e.g., State of Oklahoma ex rel Edmondson v. Tyson Foods, Inc.*, 2007 WL 649332, at *5 (N.D. Okla. Feb. 26, 2007) ("As previously ordered in this case, quality, not quantity, is the guiding discovery light for the court and counsel."); *United States v. Caso*, 935 F.2d 1288 (4th Cir. 1991) (although "forests of paper" were turned over by the government, "quantity does not make quality."); *Ropak Corp. v. Plastican, Inc.*, 2006 WL 2385297, at *5 (N.D. Ill. Aug. 15, 2006) ("The Court notes that Plastican has repeatedly called to

the Court's attention the quantity of documents produced as well as to the fact that it has expended numerous hours and money spent responding to Plaintiffs' discovery requests. However, the Court reminds Plastican that quantity is not the equivalent of quality and that the hours and money spent in responding to a discovery request, no matter how broad, are inherent costs of litigation, particularly when that response has been compelled by a United States Judge.").

B. <u>Purdue's Motion Is Moot And Unnecessary</u>.

With respect to the Requests for Production themselves, they have been rendered moot by Purdue's Court-approved rolling document production. The Court already ruled on these issues and the State is complying with that ruling.

1. <u>Purdue Frederick Co.'s Request Nos. 1, 5-6</u>:

These requests seek documents regarding the processes and criteria used by the Oklahoma Healthcare Authority to determine whether a prescription should be reimbursed, as well as documents relating to each claim submitted for reimbursement. Purdue argues the State has failed to produce responsive documents. First, as set forth above, that is incorrect. The State has produced documents, provided detailed interrogatory answers, and is continuing to produce documents. The State is making its production on a rolling basis, and it will continue to produce responsive documents as quickly as they can be gathered and reviewed for privilege. Second, on May 8, 2018, the State produced to Purdue an excel file from the Oklahoma Health Care Authority which represents Oklahoma Medicaid claims data for all opioid prescriptions for the years 1996-2017 (OHCA-00000001-2). This was not a single document, but a compilation of data from an entire database. Third, the State has directed Purdue to the Oklahoma statutes and regulations governing the State's policies on reimbursement for claims submitted to the State's Medicaid Program (*see, e.g.*, OAC § 317:30-3-1(f)). The State has also directed Purdue to publicly

accessible websites which contain the State's prescribing and dispensing guidelines, prior authorization criteria, and step edit protocols. For Purdue to argue the State has produced only a few documents in response to *Request for Production Nos. 1, 5* and 6 is disingenuous.

2. <u>Purdue Pharma L.P.'s Request No. 3</u>:

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This request seeks documents relating to any service used by the State to monitor prescribing activities or potentially suspicious prescribing of Purdue's opioids. [See Ex. 4, Purdue Pharma, L.P. First Set of Requests for Production of Documents (01/12/18) at RFP No. 3.] The State already agreed to produce de-identified documents and communications that relate to this request that are reasonably accessible and within the State's possession, custody and control. The State will comply with this request in accordance with Judge Hetherington's "rolling production" ruling as soon as reasonably possible and in plenty of time for Purdue to take depositions.

C. <u>Purdue Misleadingly Claims The State Did Not Respond To A Meet And Confer</u> <u>Request</u>.

Purdue claims that it "sought to meet and confer with State's counsel...but received no response." [See Motion at p. 4.] That is demonstrably false and misleading. Section 3237(A)(2) provides, in pertinent part, that "[t]he motion <u>must</u> include a statement that the movant has <u>in good</u> <u>faith</u> conferred or attempted to confer <u>either in person or by telephone</u> with the person or party failing to make the discovery in an effort to secure the information or material without court action."12 O.S. § 3237(A)(2) (emphasis added). Compliance is required "to lessen the burden on the court and reduce the unnecessary expenditure of resources by litigants, through the promotion of informal, extrajudicial, resolution of discovery disputes." *Nevada Power v. Monsanto*, 151 F.R.D. 118, 120 (D. Nev. 1993). The consultation obligation "[promote[s] a frank exchange between counsel to resolve issues by agreement or at least narrow and focus discovery matters in controversy before judicial resolution is sought." *Id.* The record shows Purdue attempted no good

faith meet and confer, and Purdue's representation to the contrary is false.

Purdue's counsel emailed two of the State's counsel on Thursday, August 16, 2018 at 2:45pm, asking if they were available to discuss Purdue's discovery concerns the next day on Friday. [*Ex. 5, 08/16/18 Email from Purdue's counsel.*] The State's counsel promptly responded *the very next day* and confirmed that they were available Monday, August 20 for a meet and confer. [*Ex. 6, 08/17/18 Email from State's counsel.*] Purdue never responded and filed the instant *Motion* without so much as a response. Many of the issues raised in Purdue's *Motion*, particularly with respect to the timing of the State's expected future productions, may have been resolved with a phone call between counsel and not necessitated Court involvement. This is particularly true considering three of the four discovery requests at issue in Purdue's *Motion* have already been addressed and resolved by Judge Hetherington.² [*See Ex. 1, Orders of Special Discovery Master on April 19, 2018 Motion Requests (04/25/18) at p. 3.*].

Purdue's misrepresentation is par for the course. At every turn, the State is met with Purdue's obstructionist tactics and misrepresentations, designed solely to mislead the Court, delay, and put up roadblocks in the discovery process to prevent the State from keeping its May 2019 trial date. Purdue has filed motion after motion to quash subpoenas, objected to document production at every possible opportunity, filed improper and meritless removal papers (resulting in a seven week stay of the case and unfortunate discovery delay), and prevented the State from taking even a single deposition, including those noticed <u>last spring</u>. Most recently, Purdue

² Tellingly, Purdue previously filed a frivolous *Motion to Compel*, which the State moved to strike as moot because it agreed to produce everything responsive to Purdue's requests (including the documents sought in the instant *Motion*). [See Purdue's Motion to Compel Production of Documents (04/05/18); Plaintiffs' Opposition and Motion to Strike Purdue's Motion to Compel Production of Documents as Moot (04/12/18).] In other words, last time Purdue simply ignored the State's meet and confer concessions in filing its Motion. This time Purdue decided to bypass the meet and confer process altogether.

blatantly disregarded the Court's order to provide witnesses for all depositions noticed before August 30, 2018. [See State's Emergency Motion to Show Cause for Purdue's Intentional Disregard of Two Court Orders and Failure to Provide Witness as Ordered by the Court (08/20/18).] The State has repeatedly stressed the importance of moving forward with depositions in this case, and Purdue continues to stymie the entire discovery process. Filing motions with misrepresentations that the written record clearly contradicts is just another manner in which Purdue is thumbing its nose at the entire judicial process.

Purdue's total refusal to engage in the meet and confer process represents a blatant disregard and disrespect for the discovery rules and the time and resources of this Court, and it constitutes sufficient grounds in and of itself to deny Purdue's *Motion. See, e.g., Johnson v. Old Republic Ins. Co.*, 2012 WL 1672995, at *2 (N.D. Okla. May 14, 2012) (motion to compel denied where counsel did not meet and confer in good faith in a sincere attempt to resolve their discovery differences are required by Rule 37); *Rigdon v. Flowserve Corp., et al.*, 2017 WL 2821939, at *1 (N.D. Okla. June 29, 2017) ("The court agrees it would be appropriate to deny CVR's motion for its failure to engage in the good faith conference required by Fed. R. Civ. P. 37(A)(1) and LCvR 37.1.").

CONCLUSION

For the reasons set forth above, the State respectfully requests the Court deny Purdue's *Motion to Compel Production of Documents* in its entirety.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above and foregoing was emailed on August 24, 2018 to:

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IN THE DISTRICT COURT OF CLEVELAND COUNTY STATE OF OKLAHOMA

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STATE OF OKLAHOMA, ex rel.,)	
MIKE HUNTER,	
ATTORNEY GENERAL OF OKLAHOMA,)	
)	
Plaintiff,)	· · · ·
)	Case No. CJ-2017-816
vs.)	
)	Judge Thad Balkman
(1) PURDUE PHARMA L.P.;)	
(2) PURDUE PHARMA, INC.;)	
(3) THE PURDUE FREDERICK COMPANY,)	
(4) TEVA PHARMACEUTICALS USA, INC.;)	
(5) CEPHALON, INC.;)	
(6) JOHNSON & JOHNSON;)	STATE OF OKLAHOMA S.S.
(7) JANSSEN PHARMACEUTICALS, INC,)	CLEVELAND COUNTY S.S.
(8) ORTHO-MCNEIL-JANSSEN)	
PHARMACEUTICALS, INC., n/k/a)	FILED
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n/k/a JANSSEN PHARMACEUTICALS, INC.;)	
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,)	In the office of the
f/k/a ACTAVIS, INC., f/k/a WATSON)	Court Clerk MARILYN WILLIAMS
PHARMACEUTICALS, INC.;)	
(11) WATSON LABORATORIES, INC.;)	
(12) ACTAVIS LLC; and)	
(13) ACTAVIS PHARMA, INC.,)	
f/k/a WATSON PHARMA, INC.,)	
) Defendants.	
Detenuants.	

ORDERS OF SPECIAL DISCOVERY MASTER ON APRIL 19th 2018 MOTION REQUESTS

On April 19, 2018, the above and entitled matter was heard before the undersigned on the parties' various motions, objections and requests for relief. The undersigned Special Discovery Master having reviewed the pleadings, heard oral arguments and being fully advised in the premises finds as follows:

Purdue's Motion To Compel Production Of Documents

Purdue Frederick Co.

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- 1. RFP No. 1 State's objection withdrawn during meet and confer, motion to compel **sustained**;
- 2. RFP No. 5 State's objection withdrawn during meet and confer, motion to compel **sustained**;
- 3. RFP No. 6 State's objection withdrawn during meet and confer, motion to compel **sustained**;
- 4. RFP No. 7 State's objection withdrawn during meet and confer, motion to compel sustained.

State's Second Motion To Compel

State has served notice for corporate designee depositions as described in exhibits one through six of State's motion:

- 1. The open letter published by or on behalf of the Purdue Defendants in the New York Times on Thursday, December 14, 2017, entitled, "We manufacture prescription opioids. How could we not help fight the prescription and illicit opioid abuse crisis?" ("Open letter"), including but not limited to all actions taken by Purdue Defendants in support of the recommendations and initiatives identified in the Open Letter, and the reasons the Open Letter was written and published.
- 2. The Purdue Defendants' decision to discontinue marketing or promoting opioids to prescribers.
- 3. The J&J Defendants' past and present relationship with Tasmanian Alkaloids, the corporate structure and management of Tasmanian Alkaloids during its affiliation with any J&J Defendants, and the terms of any asset purchase agreement, acquisition agreement, and/or purchase and sale agreement by and between any J&J Defendants and Tasmanian Alkaloids, including terms related to the assumption of liability.

4.-6. All actions available or necessary to address, fight, update and/or reverse the opioid epidemic. (One Notice For Each Defendant Group)

IN THE DISTRICT COURT OF CLEVELAND COUNTY STATE OF OKLAHOMA

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STATE OF OKLAHOMA, ex rel., MIKE HUNTER,	ş Ş	
ATTORNEY GENERAL OF OKLAHOMA,	§	
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Plaintiff,	§	
	§	
VS.	§	
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(1) PURDUE PHARMA L.P.;	\$\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	
(2) PURDUE PHARMA, INC.;	§	
(3) THE PURDUE FREDERICK COMPANY;	§	
(4) TEVA PHARMACEUTICALS USA, INC.;	§	
(5) CEPHALON, INC.;	ş	
(6) JOHNSON & JOHNSON;	§	
(7) JANSSEN PHARMACEUTICALS, INC.;	Ş Ş	
(8) ORTHO-MCNEIL-JANSSEN	§	
PHARMACEUTICALS, INC., n/k/a	§	Case No. CJ-2017-816
JANSSEN PHARMACEUTICALS, INC.;	Ş Ş	
(9) JANSSEN PHARMACEUTICA, INC.,	§	The Honorable Thad Balkman
n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,	§	
f/k/a ACTAVIS, INC., f/k/a WATSON	ş	JURY TRIAL DEMANDED
PHARMACEUTICALS, INC.;		
(11) WATSON LABORATORIES, INC.;	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	
(12) ACTAVIS LLC; and	§	
(13) ACTAVIS PHARMA, INC.,	§	
f/k/a WATSON PHARMA, INC.,	§	
	§	
Defendants.	§	
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PLAINTIFF'S RESPONSES AND OBJECTIONS TO DEFENDANT PURDUE PHARMA, L.P.'S FIRST SET OF INTERROGATORIES

Pursuant to 12 OKLA. STAT. §3233, Plaintiff, the State of Oklahoma (the "State" or "Plaintiff"), hereby submits its Responses and Objections to Defendant Purdue Pharma, L.P.'s ("Defendant") First Set of Interrogatories to Plaintiff. The State specifically reserves the right to supplement, amend and/or revise these Responses and Objections in accordance with 12 OKLA. STAT. §3226.

RESPONSES AND OBJECTIONS TO INTERROGATORIES

INTERROGATORY NO. 1: Describe any course of action, program, or other efforts that You or anyone acting on Your behalf considered or implemented to (i) ensure that HCPs did not write Opioid prescriptions that You claim were unnecessary, excessive, and/or not a Medical Necessity; (ii) ensure that the Programs did not reimburse claims for payment of Opioid prescriptions that You claim were unnecessary, excessive, and/or not a Medical Necessity; or (iii) attempt to recoup payments or reimbursements made by You for Opioid prescriptions that You allege were unnecessary, excessive, and/or not a Medical Necessity. For each course of action, program, or other effort identified in response to this Interrogatory, provide the dates and identify the Person(s) most knowledgeable.

RESPONSE TO INTERROGATORY NO. 1:

The State incorporates its general objections and objections to Defendant's instructions and definitions above, including the State's objections to Defendant's definitions of the terms "You," "HCPs," "Opioid," and "Program," as if fully set forth herein.

The State further objects to this Interrogatory because it requests the State describe each and every "course of action," "program," or "other effort" ever considered or implemented for ensuring that HCPs did not write and the State did not reimburse unnecessary Opioid prescriptions, and any such efforts for recovering any reimbursed claims for unnecessary Opioid prescriptions. Such a request is overbroad, unduly burdensome, disproportionate to the needs of the case and seeks information that is irrelevant to the claims and defenses at issue in this action. Any conceivably marginal relevance associated with such information is substantially outweighed by the tremendous time and expense burdens the State would have to endure to respond. The State further objects as this Interrogatory calls for information outside of the State's possession, custody, or control by seeking information related to any "course of action," "program," or "other effort" ever "considered" by anyone acting on the State's behalf. Moreover, the State objects to the request to "identify the Person(s) most knowledgeable" for the same reasons.

The State further objects to this interrogatory as impermissibly compound because it indiscriminately groups numerous separate topics, subjects, questions and tasks under the guise of a single interrogatory. In reality, this Interrogatory is actually at least four (4) separate interrogatories improperly disguised as one. *See* 12 OKLA. STAT. §3233(A). The State will reasonably and conservatively construe the Interrogatory as requesting the State to describe the courses of action, programs or other efforts the State considered or implemented to: (i) ensure that HCPs did not write opioid prescriptions that the State claims were not a Medical Necessity; (ii) ensure that the Programs did not reimburse claims for payment for opioid prescriptions that were not a Medical Necessity; (iii) attempt to recover reimbursements previously made by the State for opioid prescriptions that were not a Medical Necessity; and (iv) identify the individuals most knowledgeable about each such effort.

The State further objects to this Interrogatory because it calls for the identification and description of information protected from disclosure by the attorney-client privilege, the work-product doctrine for trial preparation materials, and other federal and State privileges and immunities. The State further objects to this Interrogatory because it calls for information that is the subject of ongoing criminal, civil and/or enforcement investigations and proceedings. The State will not compromise the confidentiality of any such proceedings.

Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

The State's principal processes, practices and procedures for ensuring that claims for reimbursement are reimbursable and relate to medically necessary treatment are primarily based on the relationship between State-imposed safeguards, implemented through regulations, and the State's trust in and reliance upon certifying parties to be fully and accurately informed and capable of accurately assessing that claims submitted for reimbursement are for medically necessary services, treatments and prescriptions. This trust is predicated on the State's reasonable reliance on the presumption that any pharmaceutical marketing activity that takes place in the State, or otherwise reaches certifying parties and patients in the State, is lawful and truthfully characterizes the risks and efficacy of the marketed pharmaceuticals in a manner that does not unduly or improperly influence or hinder the appropriate analysis of the medical necessity of prescribing any marketed pharmaceuticals.

Based on the unprecedented scope of the misinformation campaign at issue in this litigation and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their coconspirators, neither medical providers nor patients had the benefit of all material information regarding Defendants' drugs. As such, it was not possible for providers or patients to discern whether any prescription was medically necessary or to informatively consider the "medical necessity" criteria set forth in Oklahoma regulations and accurately certify the accuracy of such determinations. Defendants flooded the medical community with false and misleading information—and omitted material information—as part of a scheme and conspiracy designed to make the public believe that opioids were more effective and less addictive than they actually were. Without the benefit of all material information, and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their co-conspirators, it was not possible for providers or patients to discern whether any prescription was medically necessary.

The Medical Assistance Program ("Medicaid") is a cooperative program of the state and federal governments that provides medical assistance for the poor. *See* Title XIX of the Social Security Act of 1935, 42 U.S.C. §1396 *et seq.* While a state is not obligated to participate in a Medicaid program, if it chooses to participate, the state administers its Medicaid program, but it must operate its program in compliance with the federal Medicaid statutes and regulations. *See id.* at §1396a. The State participates in Medicaid, and the Oklahoma Health Care Authority ("OHCA") administers the Oklahoma Medicaid Program ("SoonerCare"). The State further provides prescription drug coverage under its SoonerCare program. *See* OKLA. ADMIN. CODE §317:30-5-72. Accordingly, under the federal Medicaid Act, the State is required to provide coverage for all drugs approved by the U.S. Food and Drug Administration ("FDA") that are offered by any manufacturer that enters into a basic rebate agreement in order to participate in Medicaid under the Medicaid rebate program. *See, e.g.*, 42 U.S.C. §1396r-8.

By regulation, the State cannot legally reimburse claims for reimbursement for treatment that is not medically necessary. *See, e.g.*, OKLA. ADMIN. CODE §317:30-3-1(d). However, for the Medicaid system to work and for Medicaid beneficiaries to receive the benefit of timely and efficient medical treatment and coverage, the State cannot review in real time each individual claim submitted for reimbursement to ensure the claim relates to treatment that was medically necessary. Medical providers seeking reimbursement from SoonerCare for medical services submit their claims for reimbursement to the OHCA in the form of Current Procedural Terminology ("CPT") codes—accepted numeric codes which indicate the treatment, medical decision-making, and services for which the provider seeks reimbursement. Claims for reimbursement for covered prescriptions are submitted separately by the dispensing pharmacy, such that SoonerCare typically receives two claims for reimbursement related to a single patient visit: one from the medical provider for his or her services (which are identified by CPT codes and based on the medical providers' decision-making and analysis, including any relevant diagnoses identified by ICD-9/10 codes) and one from the pharmacy for any resulting prescription (which is not accompanied by the medical provider's records or any ICD-9/10 codes). As a result, OHCA maintains separate claims databases for (1) claims and reimbursement for medical providers' services and (2) claims and reimbursement for prescriptions.

The State's ability to audit medical providers' documentation and other information that forms the basis for any claim for reimbursement is limited to the retrospective ability to determine whether a claim submitted should have been reimbursed on the back-end of the Medicaid process. On the front-end, when a claim for reimbursement is submitted, the State must and does rely upon the certification of medical necessity, which certifies that the services, treatment, products or prescriptions for which reimbursement is sought were medically necessary with each claim for reimbursement. This in turn is based, at least in part, on the State's trust and reliance upon the reasonable presumption that the totality of information available to the certifying party is not deceptive, incomplete, false and/or misleading and is not the product of fraudulent marketing activity that obscured or mischaracterized the risks and efficacy of any marketed pharmaceuticals.

Therefore, in order to allow the Medicaid system to work correctly and enable Medicaid beneficiaries to receive timely and effective medical treatment, the State has defined the standards that must be considered in determining whether medical treatment is medically necessary and requires certification that each claim submitted for reimbursement is for medically necessary treatment. The State requires entry of a standard form Provider Agreement in order to be eligible for reimbursement from SoonerCare. *See* OKLA. ADMIN. CODE §317:30-3-2. Under this Provider Agreement, it is expressly certified with each claim for payment that, amongst other things, the services or products for which payment is billed by or on behalf of the provider were medically necessary, as the State, through OHCA, has defined that term. Essential to the proper functioning of SoonerCare is the reasonable presumption that any pharmaceutical marketing that may influence the certifying party's decision-making is proper and lawful and that such medical-decision making was not unduly influenced or hindered by predatory, false, misleading, coercive, negligent or fraudulent marketing tactics, such as those at issue here.

The State has defined "[m]edical necessity" as an assessment and consideration of the following standards and conditions:

(1) Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability;

(2) Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service;

(3) Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes;

(4) Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider;

(5) Services must be delivered in the most cost-effective manner and most appropriate setting; and

(6) Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity.

OKLA. ADMIN. CODE §317:30-3-1(f). However, when parties engage in and conspire to engage in

a widespread misinformation campaign, such as Defendants did here, such conduct corrupts the

informed consideration of these criteria and, thus, the certification of these determinations.

The State notes that Defendants have pled the learned intermediary doctrine in an attempt

to blame physicians for the fallout of the opioid epidemic. The State disagrees that such a defense

is legally or factually applicable to this case. In Oklahoma, the learned intermediary defense is only available in products liability cases. See McKee v. Moore, 1982 OK 71, ¶6-8, 648 P.2d 21; Brown v. Am. Home Prods. Corp., No. 1203, 2009 U.S. Dist. LEXIS 30298, at *24 (E.D. Pa. Apr. 2, 2009). This case is not a products liability case. Therefore, the learned intermediary doctrine is not applicable. Moreover, even if it were applicable, the doctrine only shields manufacturers of prescription drugs from liability "if the manufacturer adequately warns the prescribing physicians of the dangers of the drug." Edwards, 1997 OK 22, ¶8. "To invoke a defense to liability under the learned intermediary doctrine, a manufacturer seeking its protection must provide sufficient information to the learned intermediary of the risk subsequently shown to be the proximate cause of a plaintiff's injury." Tortorelli v. Mercy Health Ctr., Inc., 2010 OK CIV APP 105, ¶27, 242 P.3d Here, Defendants intentionally *misrepresented* the risks of opioid addiction-often 549. contradicting their own labeling—in a sprawling and coordinated marketing campaign targeting doctors and others throughout Oklahoma and the country. Defendants initiated a scheme to change the way physicians think about opioids. Defendants cannot falsely market their drugs to physicians and, at the same time, claim physicians should have known better. As such, even if the learned intermediary doctrine were applicable here (which it is not), Defendants cannot take advantage of the doctrine because they failed to adequately warn of the true risks of opioids, which risks caused the opioid epidemic in Oklahoma.

Additionally, the Oklahoma State Board of Medical Licensure and Supervision the Oklahoma State Board of Pharmacy, the Oklahoma Board of Nursing, Oklahoma State Board of Dentistry, and the Oklahoma Veterinary Board have authority to grant and remove certain medical providers' licenses to prescribe Opioids in the State of Oklahoma for good cause. Further, the State implements supplementary safeguards or processes, practices and procedures designed to assist medical providers in ensuring the medical necessity of the treatments for which they seek reimbursement. For example, as it relates to the claims and defenses at issue in this litigation, the State has:

- Consistently published opioid prescribing and dispensing guidelines, including the SoonerCare Pain Management Program, designed to attempt to assist medical providers in determining when and whether to prescribe or dispense opioids;
- Implemented a Pharmacy Lock-In Program, designed to assist health care providers in monitoring potential abuse or inappropriate utilization of controlled prescription medications by SoonerCare members; and
- Implemented scope, utilization and product based controls for opioid prescriptions, including requiring prior authorization for prescriptions related to many opioids and imposing quantity limits for SoonerCare pharmacy claims for reimbursement.
- Implemented and utilized a near-real-time Prescription Monitoring Program ("PMP") to track and identify over-prescription of controlled substances, such as opioids, to Oklahoma citizens.

However, each of these safeguards, processes, practices and procedures were predicated on Oklahoma medical providers and the medical community having been fully informed and not misled as to the risks, benefits and characteristics of opioids in order to enable providers to informatively consider the medical necessity of their treatment and truthfully certify the accuracy of these assessments.

The State has devoted substantial effort and taken significant actions, including filing this lawsuit against the named Defendants, to treat, remediate, control, deter and minimize addiction to and abuse of opioids, as well as illicit prescribing and dispensing of opioids, in the State of Oklahoma since 1996. Due to the nature and extent of these widespread problems, the State's efforts to attempt to correct the misinformation related to opioids and the public health crisis this misinformation has caused in the State of Oklahoma span and have required the cooperation and coordination of numerous departments, divisions, agencies and branches of the State government, including executive agencies, law enforcement, public health, regulatory boards, health care providers and substance abuse prevention and treatment providers. Among countless others, these

efforts include the State's enactment of legislation to combat opioid over-prescription, the appointment of a special Task Force to study the economic impact of the opioid epidemic on the State by the Governor of the State of Oklahoma, the investment of substantial State funds in the State's Prescription Monitoring Program, the development of comprehensive prescription drug abuse education, intervention and prevention programs, and the investment of significant public resources to enhance the State's opioid prescribing and dispensing guidelines, public health surveillance systems and hospital emergency protocols identified in paragraphs 29, 33 and 46-49 of the State's Original Petition.

However, attempting to correct the misinformation about opioids disseminated to the medical community and the Oklahoma opioid epidemic that has followed is a monumental task for which the State continues to devote substantial ongoing efforts, including the filing of this lawsuit. Nevertheless, in addition to filing this lawsuit, many of the principal efforts the State has taken to address these subjects since 1996, as well as responsive documents, reports, studies and other materials related to these efforts, include the following:

In 2010, the State established the Oklahoma Prevention Leadership Collaborative ("OPLC") to promote coordinated planning, implementation, and evaluation of quality prevention services for children, youth, and families at the state and local levels with a particular focus on the prevention of mental, emotional and behavioral health disorders, related problems and contributing risk factors. The OPLC served as the advisory body for the Oklahoma Strategic Prevention Framework State Incentive Grant ("SPF SIG"), funded by the Substance Abuse and Mental Health Services Administration and administered by the Oklahoma Department of Mental Health and Substance Abuse Services, and focused on the prevention and treatment of prescription drug abuse as its priority. In September 2012, the OPLC commissioned a workgroup to develop a state plan,

Reducing Prescription Drug Abuse in Oklahoma. In 2013, the OPLC's Prescription Drug Planning Workgroup published a State plan aimed at reducing opioid-related overdose deaths. This plan, which identifies numerous studies, documents, reports and other materials considered by the workgroup and outlines many of the State's efforts to combat the opioid epidemic, is publicly available and can be accessed at the following URL: <u>https://www.ok.gov/odmhsas/documents/Rx</u> <u>Abuse Prevention Plan.pdf</u>. In 2016, the OPLC's Prescription Drug Planning Workgroup published a "Review of Progress and Updated State Plan," which also identifies numerous studies, documents, reports and other materials considered by the workgroup and outlines many of the State's efforts to combat the opioid epidemic. This updated plan is publicly available and can be accessed at the following URL:

https://www.ok.gov/health2/documents/UP_Rx_Abuse_Prevention_State_Plan_2016.pdf.

The Oklahoma Bureau of Narcotics and Dangerous Drug Control ("OBN") uses and administers the Prescription Monitoring Program ("PMP") to detect potentially problematic prescriptions. The PMP has been in operation, in one form or another, since at least 1990 when the program was referred to as Oklahoma Schedule Two Abuse Reduction or "O-STAR." On March 31, 2015, the Oklahoma Legislature enacted House Bill No. 1948, which imposes a mandatory requirement on all Oklahoma medical providers to check and review a patient's history in the PMP prior to prescribing and every 180 days prior to authorizing another prescription for opiates, synthetic opiates, semi-synthetic opiates, benzodiazepine, or carisoprodol. OBN is currently implementing several "alerts" in the PMP system that will alert prescribers to potential at-risk patients early in the addiction cycle in order minimize over-prescribing of opioids. For example, the PMP will alert physicians when a patient who is seeking opioids has attempted to fill prescriptions for opioids from five separate practitioners and five different pharmacies within the past 90 days. Other quantity-based and drug-specific "alerts" will be implemented on an on-going basis.

Since 2014, OBN has in various formats, alerted prescribers and pharmacies with the identities of potential opioid abusers or at-risk patients who have exhibited opioid-seeking behavior according to the PMP. OBN also identifies the top twenty prescribers of controlled dangerous substances, including opioids, to the medical licensure boards as appropriate, and also identifies the top twenty "doctor shoppers" to the appropriate entities in the State.

Since March of 2011, OBN has instituted and executed an ongoing program, entitled "Safe Trips for Scripts," whereby OBN has installed approximately 180 pharmaceutical take-back containers for the public to safely dispose of expired or excessive medications. The goal is to minimize the surplus of prescription drugs in Oklahoma communities. During this time period, over 151,000 pounds (more than 70 tons) of medications have been collected and safely disposed of through these pharmaceutical take-back containers. Additional information, including documents, reports, studies and other materials, related to the State's efforts to ensure the safe use, storage and disposal of prescription drugs, including opioids, is publicly available at the following URL:

https://www.ok.gov/health/Protective_Health/Injury_Prevention_Service/Drug_Overdose/Safe_ Use, Storage, and Disposal/index.html.

OBN has also implemented several educational efforts related to opioids. These education efforts include: (1) providing presentations and educational training regarding prescription drug abuse to law enforcement, prescribers, pharmacists, and the general public; (2) active training of OBN agents through OBN's involvement and collaboration with numerous educational organizations, including the National Association of Drug Diversion Investigators, National Association of State Controlled Substance Authorities and the Association of Oklahoma Narcotics Enforcers; and (3) active involvement with numerous coalitions, including the Injury Prevention Coalition, Rx Coalition Group and Prevention Wrkz Coalition, amongst others.

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In 2014, in conjunction with changes to federal controlled drug schedules, OBN recognized hydrocodone as a Schedule 2 controlled substance.

Around approximately 2017, OBN established its "Next Step" program, whereby OBN partnered with the Oklahoma Department of Mental Health and Substance Abuse Services and Oklahoma Health Care Authority to provide addicted individuals who meet certain criteria with substance abuse rehabilitation and addiction treatment in an effort to minimize incarceration and increase rehabilitation of addicted drug users.

In or around 2014, OBN implemented a lock-box or "drug-safe" distribution program whereby OBN distributed approximately 500 prescription drug safes or lock boxes to the Oklahoma community to minimize the illicit diversion of dangerous drugs, including opioids. In or around 2017, OBN used grant money it had received to purchase and distribute additional units of Naloxone to OBN agents and Oklahoma law enforcement officers or agencies.

In 2014, the OHCA implemented an updated Pharmacy Lock-In Program as "a new weapon in the war against prescription drug abuse," which assists health care providers in monitoring potential abuse or inappropriate utilization of controlled prescription medications by SoonerCare members. *See OHCA Adds New Measure To Combat Public Crisis Of Prescription Drug Abuse*, News Release (Mar. 24, 2014), <u>http://www.okhca.org/about.aspx?id=15752</u>. When warranted, a member may be "locked-in", and therefore required to fill all prescriptions at a single designated pharmacy in order to better manage his or her medication utilization. Under the updated Pharmacy Lock-in Program, members are also locked in to a single prescriber for all scheduled

drugs, such as opioids, benzodiazepines, and carisoprodol. Additional information regarding the OHCA's Lock-In Program, including materials related to this Program, is publicly available at the following URLs:

http://www.okhca.org/research.aspx?id=87; and

http://www.okhca.org/providers.aspx?id=8738&linkidentifier=id&itemid=8738.

In January 2016, the OHCA launched the SoonerCare Pain Management Program, which is designed to equip SoonerCare providers with the knowledge and skills to appropriately treat members with chronic pain. As an initial step, OHCA medical staff developed a proper prescribing "toolkit." The toolkit contains recommendations from national guidelines and evidence-based research on how to treat chronic pain patients. It includes patient education materials and risk assessment and functional assessment tools in addition to the prescribing guidelines. Documents, reports, studies and other materials considered by the OHCA in relation to its efforts are made publicly available on the OHCA's website and include:

- Documents regarding the OHCA's Pain Management Program (<u>http://www.okhca.org/about.aspx?id=18411</u>), including the following:
 - o The OHCA's Pain Management Toolkit;
 - o A letter from the American Academy of Family Physicians (May 20, 2016);
 - The Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids (March 15, 2016);
 - o A Letter from the U.S. Surgeon General regarding opioids (August 2016);
 - o The U.S. Surgeon General's Pocket Guide on Opioids;
 - o The U.S. Surgeon General's Report on Alcohol, Drugs and Health;
 - A powerpoint presentation regarding the OCHA's SoonerCare Pain Management Program;
 - o A powerpoint presentation regarding Opioids in Pregnancy
- Materials and information regarding the OHCA's Pharmacy Lock-In Program (http://www.okhca.org/providers.aspx?id=8738&linkidentifier=id&itemid=8738).
- Drug Utilization Review Board packets (http://www.okhca.org/about.aspx?id=9728).

The State has made additional documents, reports, studies and other materials related to the State's efforts to address Defendants' false marketing through prescriber education on the Oklahoma State Department of Health's ("DOH") website, including:

- Documents, reports, studies and other materials regarding Opioid Prescribing Guidelines (https://www.ok.gov/health/Protective_Health/Injury_Prevention_Service/Drug_Overdo se/Opioid_Prescribing_Guidelines/index.html):
 - The 2017 Oklahoma Opioid Prescribing Guidelines;
 - o The Oklahoma Opioid Dispensing Guidelines 2013;
 - o "Pocket Guide: Tapering Opioids for Chronic Pain";
 - o "Nonopioid Treatments for Chronic Pain";
 - o "Assessing Benefits and Harms of Opioid Therapy";
 - o "Calculating Total Daily Dose of Opioids for Safer Dosage";
 - o "Clinical Reminders for Prescribing Opioids";
 - o "Prescription Monitoring Program FAQs";

Similarly, the OHCA has made publicly available on its website numerous documents, reports, studies and other materials that relate to the State's efforts to treat, remediate, control, deter, or minimize addiction to opioids and opioid prescribing and dispensing, including statistics and data, studies and evaluations, annual and semi-annual reports by the OHCA and links to other resources published by the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, and Department of Health and Human Services, amongst others. <u>http://www.okhca.org/research.aspx?id=46&parts=7447</u>.

The OHCA has consistently taken efforts to limit the amount of prescriptions for narcotic analgesics in Oklahoma by implementing scope, utilization and product based controls for such prescriptions. For example, since at least 2009 and through the present, OHCA has required prior authorization for prescriptions related to many opioids. Information, data and other materials related to these prior authorization requirements is publicly available and accessible at the following URLs: <u>https://www.okhca.org/providers.aspx?id=1218</u> and <u>https://www.okhca.org/providers.aspx?id=12090#34</u>. Moreover, beginning around November

2014, the OHCA further implemented a three-phased quantity limit edit for SoonerCare pharmacy claims for reimbursement related to prescriptions for chronic opioid analgesics in order to reduce the amount of opioids prescribed in Oklahoma. Information, documents and other materials related to the OHCA's opioid analgesic quantity limitation efforts is publicly available at the following URL: <u>http://www.okhca.org/providers.aspx?id=15481</u>. The State is investigating and will continue to investigate whether and to what extent Defendants attempted to or did influence the State's development of prior authorization requirements related to opioids.

In 2017, the Oklahoma Legislature enacted legislation to form the Oklahoma Commission on Opioid Abuse. This Commission issued a Final Report on January 23, 2018, which can be accessed at the following URL: <u>http://www.oag.ok.gov/Websites/oag/images/Oklahoma</u> <u>Commission on Opioid Abuse Final Report.pdf</u>. Although this Report "is not intended to address the immense impact opioid abuse has had on the State of Oklahoma nor does it calculate the damages the State has incurred or will incur as a result of the opioid epidemic[,]" it is another example of one of the many publicly available resources that describes and identifies many of the efforts the State has taken to attempt to remediate the misinformation campaign related to opioids that has caused the opioid epidemic in the State of Oklahoma.

According to its January 23, 2018 Final Report, the Oklahoma Commission on Opioid Abuse has recommended the following legislative actions:

- Enact legislation to criminalize the trafficking of fentanyl and its analogues
- Enact legislation to mandate the use of electronic prescriptions ("e-prescribing")
- Enact a Good Samaritan Law to grant limited immunity to individuals who call to report a drug overdose
- Enact legislation, such as a tax on the manufacturers, wholesalers, and distributors of opioids, as a funding mechanism for opioid addiction treatment
- Enact legislation that would require medical clinic owners to register with the Oklahoma Bureau of Narcotics and Dangerous Drugs ("OBN")

- Enact legislation that imposes maximum quantity limits on first, second, and subsequent opioid prescriptions and includes formal patient notice and informed consent requirements
- Enact legislation that requires opioid manufacturers, wholesalers, and distributors to register with the OBN
- Enact legislation to create a Drug Overdose Fatality Review Board or Task Force to study causes of opioid overdoses and identify ways to prevent death and refer appropriate cases for criminal prosecution

In addition to these specific legislative recommendations, the Commission recommended

the following additional steps:

- Encourage use of the ODMap application by law enforcement, first responders, and health officials to track overdose events in real time so that resources can be directed to "hot-spot" areas and criminal investigations can be conducted, if necessary
- Support expanded and improved utilization of the PMP by providers and proactive programming by OBN administrators which would provide alerts to prescribers and pharmacists regarding dangerous prescription combinations, high daily dosages of opioids, and doctor-shopping
- Work together with Oklahoma's federal congressional delegation to remove the federal limits on the number of patients to whom physicians can prescribe treatment drugs like buprenorphine
- Create a statewide emergency department ("ER") discharge database to study overdose events and aftercare results
- Encourage the mandatory offering of Naloxone by prescribers and pharmacists to individuals receiving their first opioid prescription or those receiving an opioid prescription in addition to a benzodiazepine
- Provide all first responders with Naloxone and training on how to recognize signs of an overdose and how to use the drug
- Encourage nursing homes and long-term care facilities to develop best practices with regard to medication safety, storage, and disposal and to promote best practices with regard to accurately documenting patient medications
- Pursue rule changes with the appropriate medical boards to require at least one hour of continuing education for all prescribers every reporting period on proper prescribing and the risks of opioids and recognizing addiction and diversion
- Pursue rule changes with the appropriate board to require at least on hour of continuing education every reporting period for pharmacists on how to recognize signs of addiction and diversion
- Prohibit mid-level prescribers who are not trained physicians (M.D., or D.O.) from being allowed prescriptive authority for Schedule II opioids
- Propose and provide specific training for law enforcement personnel and investigators through the Oklahoma Council on Law Enforcement Education and Training ("CLEET") on handing opioid diversion investigations

- Support the expansion of insurance coverage for evidence-based pain management treatment options that do not involve opioid prescriptions
- Support federal parity laws that require insurance companies to cover addiction treatment expenses just like any other biological malady
- Continue and expand the first responder overdose program through the Department of Mental Health and Substance Abuse Services, which is providing Naloxone to first responders
- Expand the 19 community-based Naloxone programs in the State to include homeless shelters
- Make more inpatient treatment beds and outpatient treatment options immediately available
- Support the expansion of OSU's Project ECHO in order to increase the number of doctors trained in addiction medicine and increase their availability to patients in rural areas of Oklahoma
- Promote and encourage the use of SBIRT tools by primary care and other providers to increase the identification of addiction and make appropriate referrals for treatment
- Promote training for middle school and high school student athletes and coaches on the risk of addiction to opioid pain medications after sports injuries and encourage the use of early intervention screening tools
- Explore educational pilot programs for middle school and high school students on the risks of opioid addiction and early intervention tools
- Explore pilot programs for sober living on college campuses and support existing programs at OSU through DMHSAS
- Promote the establishment of drug courts in the remaining four counties that do not currently have them and encourage legislators to adequately fund drug courts and other specialty courts throughout the state

Review current drug law to determine drug court eligibility and expand eligibility in light of recent

changes in the law which made some drug possession crimes misdemeanor offenses.

To attempt to recoup payments or reimbursements made by the State for unnecessary opioid prescriptions, the State has, among other things, filed this action. Based on the unprecedented scope of the misinformation campaign at issue in this litigation, which corrupted Oklahoma healthcare providers' ability to informatively consider the "medical necessity" criteria set forth in Oklahoma regulations and truthfully certify the accuracy of such determinations, at this time and based on the information reviewed to date, the State considers every opioid prescription written in the State of Oklahoma since 1996 to have lacked the appropriate certification of "medical necessity." The false representations Defendants and their co-conspirators imbedded in the Oklahoma medical community prevented providers from being able to accurately and completely assess the "medical necessity" of Defendants' drugs for any patient in the first place. As a result, these providers' compliance certifications to Oklahoma Medicaid were based on a false understanding of the true characteristics and safety of Defendants' drugs, rendering the claims for reimbursement they submitted non-reimbursable under Oklahoma Medicaid regulations.

Additionally, the State has investigated, and continues to investigate, inappropriate claims for reimbursement submitted by medical providers. The State cannot disclose any active criminal investigation. The State will produce documents regarding any non-confidential criminal and/or civil prosecutions related to opioid prescriptions following a reasonably diligent search from reasonably accessible sources.

Terri White, Nancy Nesser, and OBN likely possess the most knowledge regarding the courses of action, programs, or other efforts the State has considered or implemented regarding preventing unnecessary Opioid prescriptions. Nancy Nesser likely possesses the most knowledge regarding the processes, practices and procedures utilized by the OHCA regarding claims submitted for reimbursement from SoonerCare.

The State will supplement its Response to this Interrogatory as additional information is gathered, reviewed and produced as a part of the State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

INTERROGATORY NO. 2: Identify all of Your current and former employees, contractors, agencies, boards, committees, and other third parties responsible for, involved in, or

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produce or otherwise disclose any protected health information until that protective order, or a substantially similar protective order, is agreed to by Defendants and/or entered by the Court.

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Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

The State hereby incorporates its response to Interrogatory No. 1 above as if fully set forth herein. The State will produce responsive business records or data from which any claims for opioids for which the State denied reimbursement can be identified and, thus, from which the answer to this Interrogatory may be derived or ascertained, and the burden of deriving or ascertaining the answer is substantially the same for Defendants as it is for the State. Specifically, the State is in the process of generating reports that will provide de-identified claims data related to each opioid prescription reimbursed or denied by the State and intends to produce (but cannot at this time guarantee the production of) such reports and data at a reasonable time pursuant to the parties' arrangements and/or any orders from the Court.

The State will supplement its Response to this Interrogatory as additional information is gathered, reviewed and produced as a part of the State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

INTERROGATORY NO. 4: Describe the processes, practices, and procedures in place during the Relevant Time Period, if any, that You or any Program(s) or Oklahoma Agency used to determine whether, under what circumstances, and to what extent an Opioid prescription Claim would be paid or reimbursed for each Program that adjudicates claims seeking the payment for or reimbursement of Opioids dispensed or prescribed to Program beneficiaries, and identify the Person(s) most knowledgeable about Opioids claims processing for each Program.

RESPONSE TO INTERROGATORY NO. 4:

The State incorporates its general objections and objections to Defendant's instructions and definitions above, including the State's objections to Defendant's definitions of the terms "Relevant Time Period," "Oklahoma Agency," "Program," "Opioid," and "Claim" as if fully set forth herein.

The State further objects to this Interrogatory as impermissibly compound because it indiscriminately groups numerous separate topics, subjects, questions and tasks under the guise of a single interrogatory. In reality, this interrogatory is actually at least two (2) separate interrogatories improperly disguised as one. *See* 12 OKLA. STAT. §3233(A). The State will reasonably and conservatively construe the request to: (i) "Describe the processes...used to determine whether....an Opioid prescription Claim would be paid or reimbursed for each Program"; and (ii) "identify the Person(s) most knowledgeable" about such processes.

Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

The State hereby incorporates its response to Interrogatory No. 1 above as if fully set forth herein. The State's principal processes, practices and procedures for ensuring that claims for reimbursement are reimbursable and relate to medically necessary treatment are primarily based on the relationship between State-imposed safeguards, implemented through regulations, and the State's trust in and reliance that medical providers are fully and accurately informed and capable of accurately assessing that claims submitted for reimbursement are for medically necessary services, treatments and prescriptions. This trust is based in part on the State's reasonable reliance on the presumption that any pharmaceutical marketing activity that takes place in the State or otherwise reaches medical providers in the State is lawful and truthfully characterizes the risks and efficacy of the marketed pharmaceuticals in a manner that does not unduly or improperly influence or hinder medical providers' ability to engage in the appropriate analysis of the medical necessity of prescribing any marketed pharmaceuticals.

Based on the unprecedented scope of the misinformation campaign at issue in this litigation, Defendants corrupted Oklahoma healthcare providers' ability to informatively consider the "medical necessity" criteria set forth in Oklahoma regulations and truthfully certify the accuracy of such determinations. Defendants flooded the medical community with false and misleading information designed to make healthcare providers, including Oklahoma healthcare providers, believe that opioids were more effective and less addictive than they actually were. Without the benefit of all material information, and given the fact that the totality of information that was available was conflated with the misleading, false, and deceptive information disseminated by Defendants and their co-conspirators, it was not possible for providers or patients to discern whether any prescription was medically necessary.

The Medical Assistance Program ("Medicaid") is a cooperative program of the state and federal governments that provides medical assistance for the poor. *See* Title XIX of the Social Security Act of 1935, 42 U.S.C. §1396 *et seq*. While a state is not obligated to participate in a Medicaid program, if it chooses to participate, the state administers its Medicaid program, but it must operate its program in compliance with the federal Medicaid statutes and regulations. *See id* at §1396a. The State participates in Medicaid, and the Oklahoma Health Care Authority ("OHCA") administers the Oklahoma Medicaid Program ("SoonerCare"). The State further provides prescription drug coverage under its SoonerCare program. *See* OKLA. ADMIN. CODE §317:30-5-72. Accordingly, under the federal Medicaid Act, the State is required to provide coverage for all drugs approved by the U.S. Food and Drug Administration ("FDA") that are

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offered by any manufacturer that enters into a basic rebate agreement in order to participate in Medicaid under the Medicaid rebate program. See, e.g., 42 U.S.C. §1396r-8.

By regulation, the State cannot legally reimburse claims for reimbursement for treatment that is not medically necessary. *See, e.g.*, OKLA. ADMIN. CODE §317:30-3-1(d). However, for the Medicaid system to work and for Medicaid beneficiaries to receive the benefit of timely and efficient medical treatment and coverage, the State cannot review in real time each individual claim submitted for reimbursement to ensure the claim relates to treatment that was medically necessary. Medical providers seeking reimbursement from SoonerCare for medical services submit their claims for reimbursement to the OHCA in the form of Current Procedural Terminology ("CPT") codes—accepted numeric codes which indicate the treatment, medical decision-making, and services for which the provider seeks reimbursement.

Claims for reimbursement for covered prescriptions are submitted separately by the dispensing pharmacy, such that SoonerCare typically receives two claims for reimbursement related to a single patient visit: one from the medical provider for his or her services (which are identified by CPT codes and based on the medical providers' decision-making and analysis, including any relevant diagnoses identified by ICD-9/10 codes) and one from the pharmacy for any resulting prescription (which is not accompanied by the medical provider's records or any ICD-9/10 codes). As a result, OHCA maintains separate claims databases for (1) claims and reimbursement for medical providers' services and (2) claims and reimbursement for prescriptions.

While the State maintains the ability to audit medical providers' documentation and other information that forms the basis for any claim for reimbursement from SoonerCare, such auditing authority only provides the State with the retrospective ability to determine whether a claim submitted should have been reimbursed on the back-end of the Medicaid process. On the frontend, when a provider submits a claim for reimbursement, the State must and does rely upon the certification of medical necessity, which certifies that the services, treatment, products or prescriptions for which reimbursement is sought were medically necessary with each claim for reimbursement. This in turn is based, at least in part, on the State's trust and reliance upon the reasonable presumption that the medical provider has not been unduly or improperly influenced or hindered by fraudulent marketing activity that obscured or mischaracterized the risks and efficacy of any marketed pharmaceuticals.

Therefore, in order to allow the Medicaid system to work correctly and enable Medicaid beneficiaries to receive timely and effective medical treatment, the State has defined the standards that must be considered in determining whether medical treatment is medically necessary and requires certification that each claim for reimbursement is for medically necessary treatment. The State requires each medical provider to enter a standard form Provider Agreement in order to be eligible for reimbursement from SoonerCare. *See* OKLA. ADMIN. CODE §317:30-3-2. Under this Provider Agreement, every medical provider expressly certifies with each claim for payment that, amongst other things, the services or products for which payment is billed by or on behalf of the provider were medically necessary, as the State, through OHCA, has defined that term. Essential to the proper functioning of SoonerCare is the reasonable presumption that any pharmaceutical marketing that may influence the certifying party's decision-making is proper and lawful and that such medical-decision making was not unduly influenced or hindered by predatory, false, misleading, coercive, negligent or fraudulent marketing tactics, such as those at issue here.

The State has defined "[m]edical necessity" as an assessment and consideration of the following standards and conditions:

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(1) Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability;

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(2) Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service;

(3) Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes;

(4) Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider;

(5) Services must be delivered in the most cost-effective manner and most appropriate setting; and

(6) Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity.

OKLA. ADMIN. CODE §317:30-3-1(f). However, when parties engage in and conspire to engage in a widespread misinformation campaign, such as Defendants did here, such conduct corrupts the informed consideration of these criteria and, thus, the certification of these determinations.

The State notes that Defendants have pled the learned intermediary doctrine in an attempt to blame physicians for the fallout of the opioid epidemic. The State disagrees that such a defense is legally or factually applicable to this case. In Oklahoma, the learned intermediary defense is only available in products liability cases. *See McKee v. Moore*, 1982 OK 71, ¶¶6–8, 648 P.2d 21; *Brown v. Am. Home Prods. Corp.*, No. 1203, 2009 U.S. Dist. LEXIS 30298, at *24 (E.D. Pa. Apr. 2, 2009). This case is not a products liability case. Therefore, the learned intermediary doctrine is not applicable. Moreover, even if it were applicable, the doctrine only shields manufacturers of prescription drugs from liability "if the manufacturer adequately warns the prescribing physicians of the dangers of the drug." Edwards, 1997 OK 22, ¶8. "To invoke a defense to liability under the learned intermediary doctrine, a manufacturer seeking its protection must provide sufficient information to the learned intermediary of the risk subsequently shown to be the proximate cause of a plaintiff's injury." *Tortorelli v. Mercy Health Ctr., Inc.*, 2010 OK CIV APP 105, ¶27, 242 P.3d

549. Here, Defendants intentionally *misrepresented* the risks of opioid addiction—often contradicting their own labeling—in a sprawling and coordinated marketing campaign targeting doctors and others throughout Oklahoma and the country. Defendants initiated a scheme to change the way physicians think about opioids. Defendants cannot falsely market their drugs to physicians and, at the same time, claim physicians should have known better. As such, even if the learned intermediary doctrine were applicable here (which it is not), Defendants cannot take advantage of the doctrine because they failed to adequately warn of the true risks of opioids, which risks caused the opioid epidemic in Oklahoma.

Additionally, the Oklahoma State Board of Medical Licensure and Supervision, the Oklahoma State Board of Pharmacy, the Oklahoma Board of Nursing, Oklahoma State Board of Dentistry, and the Oklahoma Veterinary Board have authority to grant and remove certain medical providers' licenses to prescribe Opioids in the State of Oklahoma for good cause. Further, the State implements supplementary safeguards or processes, practices and procedures designed to assist medical providers in ensuring the medical necessity of the treatments for which they seek reimbursement. For example, as it relates to the claims and defenses at issue in this litigation, the State has:

- Consistently published opioid prescribing and dispensing guidelines, including the SoonerCare Pain Management Program, designed to attempt to assist medical providers in determining when and whether to prescribe or dispense opioids;
- Implemented a Pharmacy Lock-In Program, designed to assist health care providers in monitoring potential abuse or inappropriate utilization of controlled prescription medications by SoonerCare members; and
- Implemented scope, utilization and product based controls for opioid prescriptions, including requiring prior authorization for prescriptions related to many opioids and imposing quantity limits for SoonerCare pharmacy claims for reimbursement.
- Implemented and utilized a near-real-time Prescription Monitoring Program ("PMP") to track and identify over-prescription of controlled substances, such as opioids, to Oklahoma citizens.

However, each of these safeguards, processes, practices and procedures were predicated on Oklahoma medical providers and the medical community having been fully informed and not misled as to the risks, benefits and characteristics of opioids in order to enable providers to informatively consider the medical necessity of their treatment and truthfully certify the accuracy of these assessments.

Nancy Nesser likely possesses the most knowledge regarding the processes, practices and procedures utilized by the OHCA regarding claims submitted for reimbursement from SoonerCare.

The State will supplement its Response to this Interrogatory as additional information is gathered, reviewed and produced as a part of the State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

INTERROGATORY NO. 5: Identify the Persons, methods, criteria, information, reports, studies, and medical or scientific research that You, anyone acting on Your behalf, or any Program(s) or Oklahoma Agency considered, used, consulted, or relied on during the Relevant Time Period in determining whether a Claim for an Opioid prescription involved a Medical Necessity and was otherwise eligible for payment for each Program identified in response to Interrogatory No. 4.

RESPONSE TO INTERROGATORY NO. 5:

The State incorporates its general objections and objections to Defendant's instructions and definitions above, including the State's objections to Defendant's definitions of the terms "Relevant Time Period," "You," "Oklahoma Agency," "Program," "Opioid," and "Claim," as if fully set forth herein.

The State further objects to this Interrogatory because it is a premature contention interrogatory that attempts to force the State to marshal all of its evidence, including expert evidence, before any meaningful discovery has taken place in this action. *See* 12 OKLA. STAT. §3233(B). To the extent the State can respond to this Interrogatory at this preliminary stage, the State will do so based on the information currently known to and within the possession, custody and control of the State following a reasonably diligent investigation and will supplement and/or amend its response in due course according to 12 OKLA. STAT. §3226. Moreover, because this Interrogatory primarily seeks the identity of documents and materials at this preliminary stage of discovery while the State is reasonably collecting, gathering, investigating, reviewing and searching for such responsive documents, the State will supplement and/or amend its response to this Interrogatory in accordance with 12 OKLA. STAT. §3226 and 12 OKLA. STAT. §3233(C). Further, the State will produce and disclose expert information, including the expert "methods, criteria, information, reports, studies, and medical or scientific research" called for by this Interrogatory, in accordance with the scheduling Order entered by the Court.

The State further objects to this interrogatory as overbroad, unduly burdensome, vague, ambiguous, disproportionate to the needs of the case, calling for information that is not within the State's possession, custody or control, and seeking information that is irrelevant to the claims and defenses at issue in this case. Specifically, by requesting the identification of every piece of information that was ever "considered," "used," "consulted," or "relied on" in reviewing each of the many thousands of "claims" submitted to the State for the past decade, the Interrogatory necessarily encompasses an incredibly broad array of information that has no bearing on the specific issues involved in this case and that is not within the State's possession, custody or control. Much of this information is irrelevant to the claims and defenses at issue in this case or, to the

extent such information has any marginal or limited relevance whatsoever, it is substantially outweighed by the incredible time and expense burden the State would have to endure. Moreover, by requesting detailed information regarding every one of the many thousands, if not millions, of "claim[s]" submitted to the State over the past decade, the Interrogatory is inherently overbroad and unreasonable.

The State further objects to this interrogatory as impermissibly compound because it indiscriminately groups numerous separate topics, subjects, questions and tasks under the guise of a single interrogatory. In reality, this Interrogatory is actually at least two (2) separate interrogatories improperly disguised as one. *See* 12 OKLA. STAT. §3233(A). By seeking detailed information regarding every one of the many thousands, if not millions, of "claim[s]" submitted to the State over the past decade and further requesting detailed information "for each Program" inquired about in the Interrogatory, the Interrogatory realistically includes thousands of separate and individual questions. However, the State will reasonably and conservatively construe the Interrogatory, as it relates to the claims and defenses at issue, as requesting the State to: (i) "Identify the…methods, criteria, information, reports, studies, and medical or scientific research... considered, used, consulted, or relied on...in determining whether a Claim for an Opioid prescription involved a Medical Necessity."

Subject to and without waiving the foregoing objections (including those incorporated into this response), the State responds as follows:

The State hereby incorporates its response to Interrogatory No. 1 above as if fully set forth herein. The State's principal methods and criteria for determining whether medical treatment is

medically necessary and, thus, whether a claim is reimbursable by SoonerCare are set forth in the

Oklahoma Administrative Code and require the consideration by the prescribing medical

professional of the following standards:

(1) Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability;

(2) Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service;

(3) Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes;

(4) Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider;

(5) Services must be delivered in the most cost-effective manner and most appropriate setting; and

(6) Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity.

OKLA. ADMIN. CODE §317:30-3-1(f). However, when parties engage in and conspire to engage in

a widespread misinformation campaign, such as Defendants did here, such conduct corrupts the

informed consideration of these criteria and, thus, the certification of these determinations.

The State notes that Defendants have pled the learned intermediary doctrine in an attempt to blame physicians for the fallout of the opioid epidemic. The State disagrees that such a defense is legally or factually applicable to this case. In Oklahoma, the learned intermediary defense is only available in products liability cases. *See McKee v. Moore*, 1982 OK 71, ¶¶6–8, 648 P.2d 21; *Brown v. Am. Home Prods. Corp.*, No. 1203, 2009 U.S. Dist. LEXIS 30298, at *24 (E.D. Pa. Apr. 2, 2009). This case is not a products liability case. Therefore, the learned intermediary doctrine is not applicable. Moreover, even if it were applicable, the doctrine only shields manufacturers of prescription drugs from liability "if the manufacturer adequately warns the prescribing physicians of the dangers of the drug." Edwards, 1997 OK 22, ¶8. "To invoke a defense to liability under the learned intermediary doctrine, a manufacturer seeking its protection must provide sufficient information to the learned intermediary of the risk subsequently shown to be the proximate cause of a plaintiff's injury." *Tortorelli v. Mercy Health Ctr., Inc.*, 2010 OK CIV APP 105, ¶27, 242 P.3d 549. Here, Defendants intentionally *misrepresented* the risks of opioid addiction—often contradicting their own labeling—in a sprawling and coordinated marketing campaign targeting doctors and others throughout Oklahoma and the country. Defendants initiated a scheme to change the way physicians think about opioids. Defendants cannot falsely market their drugs to physicians and, at the same time, claim physicians should have known better. As such, even if the learned intermediary doctrine were applicable here (which it is not), Defendants cannot take advantage of the doctrine because they failed to adequately warn of the true risks of opioids, which risks caused the opioid epidemic in Oklahoma.

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Although the State's investigation is ongoing and the State is in the process of searching for responsive information, reports, studies, research, documents and other materials requested by this Interrogatory, the State has made many such documents and materials the State has generally considered or used publicly available on State-controlled websites. For example, such documents and other materials include:

- The Oklahoma Prevention Leadership Collaborative ("OPLC") Prescription Drug Planning Workgroup's 2013 State Plan for Reducing Prescription Drug Abuse in Oklahoma, available at: <u>https://www.ok.gov/odmhsas/documents/Rx Abuse</u> <u>Prevention Plan.pdf;</u>
- The OPLC Prescription Drug Planning Workgroup's 2016 "Review of Progress and Updated State Plan," available at: <u>https://www.ok.gov/health2/documents/UP_Rx_Abuse_Prevention_State_Plan_20_16.pdf;</u>
- Information and materials related to the OHCA's Pharmacy Lock-In Program, available at:
 - http://www.okhca.org/providers.aspx?id=8738&linkidentifier=id&itemid=8738;
- Documents regarding the OHCA's Pain Management Program (<u>http://www.okhca.org/about.aspx?id=18411</u>), including the following:
 - o The OHCA's Pain Management Toolkit;
 - A letter from the American Academy of Family Physicians (May 20, 2016);

- The Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids (March 15, 2016);
- A Letter from the U.S. Surgeon General regarding opioids (August 2016);
- o The U.S. Surgeon General's Pocket Guide on Opioids;
- The U.S. Surgeon General's Report on Alcohol, Drugs and Health;
- A powerpoint presentation regarding the OCHA's SoonerCare Pain Management Program;
- A powerpoint presentation regarding Opioids in Pregnancy
- Documents, reports, studies and other materials regarding Opioid Prescribing Guidelines, available on the Oklahoma Department of Health's ("DOH") website (https://www.ok.gov/health/Protective_Health/Injury_Prevention_Service/Drug_O verdose/Opioid_Prescribing_Guidelines/index.html), including the following:
 - The 2017 Oklahoma Opioid Prescribing Guidelines;
 - o The Oklahoma Opioid Dispensing Guidelines 2013;
 - o "Pocket Guide: Tapering Opioids for Chronic Pain";
 - o "Nonopioid Treatments for Chronic Pain";
 - "Assessing Benefits and Harms of Opioid Therapy";
 - o "Calculating Total Daily Dose of Opioids for Safer Dosage";
 - o "Clinical Reminders for Prescribing Opioids";
 - "Prescription Monitoring Program FAQs";
 - o "Overdose Prevention Handout";
 - o "Overdose Prevention Brochure";
 - o "Overdose Prevention Bookmark";
 - "Fact Sheet: Naloxone A Guide for Overdose Prevention"
- Data Reports regarding prescription drug overdoses and poisoning deaths (<u>https://www.ok.gov/health/Protective_Health/Injury_Prevention_Service/Drug_O_verdose/Data_Resources/index.html</u>), including the following:
 - o "Drug Overdose Deaths, 1999-2013: A Public Health Crisis Continues";
 - "Evaluation Summary: Oklahoma Emergency Department and Urgent Care Clinic Prescribing Guidelines";
 - o "Unintentional Poisoning Deaths in Oklahoma, 2007-2012"
- Peer-reviewed articles regarding prescription drug addiction and overdose deaths (<u>https://www.ok.gov/health/Protective_Health/Injury_Prevention_Service/Drug_O_verdose/Data_Resources/index.html</u>), including the following:
 - Prescription Drug Misuse and Associated Risk Behaviors among Public High School Students in Oklahoma: Data from the 2013 Oklahoma Youth Risk Behavior Survey, J. Okla. State Med. Assoc. 2016 Mar; 109(3): 103-10;
 - Drug Overdose Deaths: Let's Get Specific, Public Health Rep. 2015 Jul-Aug; 130(4):339-42;
 - Increases in Heroin Overdose Deaths 28 States, 2010 to 2012, MMWR Morb Mortal Wkly Rep. 2014 Oct 3; 63(39): 849-54;
 - The Association of Pseudoephedrine Sales Restrictions on Emergency Department Urine Drug Screen Results in Oklahoma, Journal of the Oklahoma State Medical Association, Nov 2007; 100(11):436-439;

- Increase in unintentional medication overdose deaths: Oklahoma, 1994-2006, American Journal of Preventive Medicine, 2010 Oct; 39(4):357-63;
- Opioid prescribing guidelines for Oklahoma emergency departments and urgent care clinics, Journal of the Oklahoma State Medical Association, Oct 2013; 106(10):391-397.
- Opioid prescribing guidelines for Oklahoma emergency departments and urgent care clinics, Journal of the Oklahoma Osteopathic Association, Oct 2013;78(4): 32-39
- Education materials related to prescription drug addiction on the DOH's website (https://www.ok.gov/health/Protective_Health/Injury_Prevention_Service/Drug_Overdose/Data_Resources/index.html), including the following materials:
 - o "Pocket Guide; Tapering"

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- o "Nonopioid Treatments";
- o "Assessing Benefits and Harms of Opioid Therapy";
- o "Calculating Total Daily Dose of Opioids for Safer Dosage";
- o "Clinical Reminders for Prescribing Opioids";
- o "Fact Sheet: Opioid Overdose in Oklahoma";
- o "Fact Sheet: Understanding the Science of Addiction";
- o "Prescription Monitoring Program FAQs";
- "Overdose Prevention Handout";
- o "Overdose Prevention Brochure";
- "Overdose Prevention Bookmark";
- "Fact Sheet: Naloxone A Guide for Overdose Prevention";
- o "Fact Sheet: Medication Safety Tips for Seniors";
- o "Fact Sheet: Unintentional Poisonings";
- "Fact Sheets: Unintentional Poisonings by County";
- o "Fact Sheet for Parents of Student Athletes"
- DOH materials regarding Opioid Overdose Prevention, available at: <u>https://www.ok.gov/health/Protective Health/Injury Prevention Service/CDC_Op</u> <u>ioid Overdose Prevention.html</u>.
- Drug Utilization Review Board packets available at <u>http://www.okhca.org/about.aspx?id=9728</u>.

Other information related to the State's consideration of the medical necessity of opioid-

related treatments, includes, but is not limited to, information which is incorporated herein by reference, as identified by citation or reference in: (i) the State's Original Petition, filed on June 30, 2017; (ii) The State's Omnibus Response to Defendants' Motions to Dismiss, filed on October 30, 2017; and (iii) the State's Response to Interrogatory Nos. 1-4 above.

The State will supplement its Response to this Interrogatory as additional documents, information, reports, studies and research is gathered, reviewed and produced as a part of the

State's ongoing investigation and reasonably diligent search for information responsive to Defendants' Interrogatories and Requests for Production of Documents.

DATED: February 14, 2018.

Respectfully submitted,

Reggie Whitten, OBA Xo. 9576 Michael Burrage, OBA No. 1350 WHITTEN BURRAGE 512 North Broadway Avenue, Suite 300 Oklahoma City, OK 73102 Telephone: (405) 516-7800 Facsimile: (405) 516-7859 Email: rwhitten@whittenburragelaw.com mburrage@whittenburragelaw.com

Mike Hunter, OBA No. 4503 ATTORNEY GENERAL FOR THE STATE OF OKLAHOMA Abby Dillsaver, OBA No. 20675 GENERAL COUNSEL TO THE ATTORNEY **GENERAL** Ethan A. Shaner, OBA No. 30916 DEPUTY GENERAL COUNSEL 313 N.E. 21st Street Oklahoma City, OK 73105 Telephone: (405) 521-3921 Facsimile: (405) 521-6246 Email: abby.dilsaver@oag.ok.gov ethan.shaner@oag.ok.gov

Bradley E. Beckworth, OBA No. 19982 Jeffrey J. Angelovich, OBA No. 19981 NIX, PATTERSON & ROACH, LLP 512 North Broadway Avenue, Suite 200 Oklahoma City, OK 73102 Telephone: (405) 516-7800 Facsimile: (405) 516-7859 Email: bbeckworth@nixlaw.com jangelovich@nixlaw.com

1	IN THE DISTRICT COURT OF CLEVELAND COUNTY		
2	STATE OF	OKLAHOMA	
3	STATE OF OKLAHOMA, ex rel.,)		
4	MIKE HUNTER) ATTORNEY GENERAL OF OKLAHOMA,)		
5) Plaintiff,)		
6) vs.	Case No. CJ-2	2017-816
7	(1) PURDUE PHARMA L.P.;)		
8	 (1) PORDOL FINIAL LIFT, (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK 		
	COMPANY;		
9	(4) TEVA PHARMACEUTICALS) USA, INC;)		
10	<pre>(5) CEPHALON, INC.;) (6) JOHNSON & JOHNSON;)</pre>		
11	<pre>(7) JANSSEN PHARMACEUTICALS,) INC.;</pre>		
12	<pre>(8) ORTHO-McNEIL-JANSSEN) PHARMACEUTICALS, INC.,)</pre>		
13	n/k/a JANSSEN PHARMACEUTICALS;)		
14	(9) JANSSEN PHARMACEUTICA, INC.) n/k/a JANSSEN PHARMACEUTICALS,)		
15	INC.;) (10) ALLERGAN, PLC, f/k/a)		
16	ACTAVIS PLC, f/k/a ACTAVIS,) INC., f/k/a WATSON)		
17	PHARMACEUTICALS, INC.;) (11) WATSON LABORATORIES, INC.;)		
18	<pre>(12) ACTAVIS LLC; AND) (13) ACTAVIS PHARMA, INC.,)</pre>		
19	f/k/a WATSON PHARMA, INC.,)		
	Defendants.)		
20			
21	TRANSCRIPT OF PROCEEDINGS HAD ON AUGUST 10, 2018		
22	AT THE CLEVELAND COUNTY COURTHOUSE BEFORE THE HONORABLE THAD BALKMAN		
23	DISTRI AND WILLIAM C. HE	CT JUDGE THERINGTON, JR	
24	RETIRED ACTIVE JUDGE AND	•	
25	REPORTED BY: ANGELA THAGARD, CS	R, RPR	2
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1 them. So they're noticed. I think we need to have this 2 hearing.

And you know, what Mr. Bartle said is true. I think we all get along pretty well here. I mean, everybody goes home to their significant others and children, whatever they have, and lives a normal life. It is an adversarial process. But that adversarial nature's often driven by the client and what they're up against.

9 So I would encourage you, if you haven't done it -- I know 10 Judge Hetherington has -- read the meet and confers and the 11 transcripts of the recorded meet and confers. They're torture. 12 You think this is bad? Come to our office one day if you have 13 time and sit for six hours and listen to 15 attorneys talk 14 about just the most ridiculous minutia in the world.

15 THE COURT: I've been having trouble sleeping at 16 night.

MR. BECKWORTH: Yeah. Well, that'll help you. I usually just kind of walk around. But we need this if we're going to move forward.

And just one thing I would like to add about this whole process -- well, two things. Number one, on timing, if they want to take depositions of our clients, they've got a lot of time to do it. As Mr. Whitten once told Judge Hetherington, we'll make ourselves available. They've got plenty of time. They don't have the documents they need? They'll get them.

DISTRICT COURT OF OKLAHOMA - OFFICIAL TRANSCRIPT

1 They can take those depositions.

We're going forward on some of these without having reviewed everything. We're doing the best we can. But I do want to bring this all back home for a moment. Mr. Whitten started with proportionality, and I know it's a relatively new rule in federal court and state court, but it does mean something.

Just because they produce several million pages doesn't mean we're going to have the same amount, nor does it mean we have to. And just because it's difficult for people to come in and spend time being deposed, you know, that's a choice that was made when this conduct started.

Purdue itself hired over a thousand sales reps and then went to Abbott and got over a thousand more, and they deployed them like soldiers throughout this country to market these drugs --

MR. COATS: I object, your Honor.

MR. BECKWORTH: -- fraudulently.

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MR. COATS: This has nothing to do with what we're talking about.

MR. BECKWORTH: It absolutely does --THE COURT: Overruled.

23 MR. BECKWORTH: -- because they were convicted of a 24 crime for it, and we can never forget that. The State of 25 Oklahoma and the citizens of this state, the families of this

IN THE DISTRICT COURT OF CLEVELAND COUNTY STATE OF OKLAHOMA

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STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,			
Plaintiff,			
vs.			
PURDUE PHARMA L.P., et al,			
Defendants.			

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Case No. CJ-2017-816

DEFENDANT PURDUE PHARMA, L.P.'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS FROM PLAINTIFF

Pursuant to 12 O.S. § 3234, Defendant Purdue Pharma, L.P. ("Purdue Pharma") requests that the Plaintiff State of Oklahoma ("the State") respond to Purdue Pharma within 30 days to this request to produce the below-described documents which are in the State's possession, custody, or control.

INSTRUCTIONS

1. Unless otherwise set forth, the documents requested include all documents created within the Relevant Time Period and continuing through the date of this request.

2. The documents requested shall be produced as they are kept in the usual course of business or shall be organized and labeled to correspond with the categories in the request.

3. You should produce electronically stored information ("ESI") and hardcopy documents in a single-page TIFF-image format with extracted or OCR text and associated metadata—a standard format in e-discovery—known as TIFF-plus. Produce electronic spreadsheets (e.g., Excel), electronic presentations (e.g., PowerPoint), desktop databases (e.g.,

3. All Documents and Communications relating to any system or service used by You or anyone acting on Your behalf to monitor prescribing activities or potentially suspicious prescribing of the Relevant Medications.

. . . .

4. All Documents and Communications concerning or relating to any assessment of actual or potential harm to Patients or other individuals as a result of the Relevant Medications or any Defendants' marketing, Educational Activities, or statements about the Relevant Medications.

5. All Documents and Communications relating to or any evaluation, assessment, analysis, modeling, or review of any financial or economic impact associated with coverage of the Relevant Medications, including the use of Opioids to treat any cause of pain (e.g., acute, chronic, cancer, or non-cancer causes of pain).

6. All Documents and Communications relating to the risks, benefits, safety, side effects, or efficacy of the Relevant Medications, including but not limited to Documents and Communications relating to summaries, studies, and/or analyses of any potential, alleged, or actual risks associated with any of the Relevant Medications.

7. All Documents and Communications relating to the creation or modification of any therapeutic intervention or switching programs (or any other program intended to encourage Medicaid or other Program beneficiaries or their physicians to switch to different medications or treatments) related to the Relevant Medications.

8. All Documents and Communications reflecting or relating to any Health Care Provider's decision whether to prescribe or dispense a Relevant Medication.

9. All Documents and Communications received by any non-parties pursuant to subpoenas that You have issued in connection with the pending litigation.

From:	LaFata, Paul <	
Sent:	Thursday, Aug	
То:	Drew Pate; 'Ll	
Cc:	Tam, Jonatha	
Subject:	Ok v. Purdue	

aFata, Paul <Paul.LaFata@dechert.com> hursday, August 16, 2018 2:46 PM rew Pate; 'Lloyd "Trey" Nolan Duck, III' am, Jonathan; Sanford C. Coats; Joshua Burns k v. Purdue

Good afternoon Trey and Drew – missed you all in Norman last week. Would one of you be available to talk tomorrow about where things are with producing documents per Purdue Pharma LP RFP No. 3 and Purdue Frederick RFP No. 1, 5, *e.g.*, 10:30-11 EST (9:30-10 CST)

Thank you,

Paul

Paul LaFata Counsel

Dechert LLP Three Bryant Park New York, New York 10036 +1 212-698-3539 Tel Paul.LaFata@dechert.com dechert.com

This e-mail is from Dechert LLP, a law firm, and may contain information that is confidential or privileged. If you are not the intended recipient, do not read, copy or distribute the e-mail or any attachments. Instead, please notify the sender and delete the e-mail and any attachments. Thank you.

From: Sent: To: Cc: Subject: Drew Pate <dpate@nixlaw.com> Friday, August 17, 2018 5:36 PM LaFata, Paul Trey Duck; Tam, Jonathan; Sanford C. Coats; Joshua Burns Re: Ok v. Purdue

Paul,

I've been traveling today. How about noon central on Monday?

Thanks,

Drew

Sent from my iPhone

On Aug 16, 2018, at 2:45 PM, LaFata, Paul <<u>Paul.LaFata@dechert.com</u>> wrote:

Good afternoon Trey and Drew – missed you all in Norman last week. Would one of you be available to talk tomorrow about where things are with producing documents per Purdue Pharma LP RFP No. 3 and Purdue Frederick RFP No. 1, 5, *e.g.*, 10:30-11 EST (9:30-10 CST)

Thank you,

Paul

Paul LaFata Counsel

Dechert LLP Three Bryant Park New York, New York 10036 +1 212-698-3539 Tel Paul.LaFata@dechert.com dechert.com

This e-mail is from Dechert LLP, a law firm, and may contain information that is confidential or privileged. If you are not the intended recipient, do not read, copy or distribute the e-mail or any attachments. Instead, please notify the sender and delete the e-mail and any attachments. Thank you.